DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NDA 50-718

Food and Drug Administration
Rockville MD 20857

SEQUUS Pharmaceuticals, Inc.
960 Hamilton Court
Menlo Park, California 94025

NOV 17 1995

Attention: Carl F. Grove
Vice President, Regulatory Affairs

Dear Mr. Grove:

Please refer to your September 2, 1994 new drug application submitted under section 507 of the Federal Food, Drug, and Cosmetic Act for DOXIL (doxorubicin HCl liposome injection) 2 mg/mL.

We acknowledge receipt of your amendments dated September 15 and 28, November 18 and December 2, 1994; February 13 and 28, March 3 and 7, April 7 and 13, May 4 and 17, June 2, July 13, August 4 and 17, September 22, October 13, 16, 27 and 31 and November 10, 1995.

This application provides for the treatment of Kaposi's Sarcoma in AIDS patients with disease that has progressed on prior combination chemotherapy or in patients who are intolerant to such therapy.

We have completed the review of this application including the submitted draft labeling under the policies and procedures reflected in the Accelerated Approval Regulations 21 CFR 314.500. We have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the November 10, 1995 draft labeling including draft carton and container labeling. Accordingly, the application is approved effective on the date of this letter.

Products approved under the Accelerated Approval Regulations 21 CFR 314.500 require further adequate and well-controlled studies to verify and describe clinical benefit. In this regard, we acknowledge your commitment in your letter dated June 28, 1995 to conduct a controlled clinical trial and request that you submit the complete findings of this study as soon as possible for our review to satisfy the requirements of the Accelerated Approval Regulations.

The approval and subsequent marketing of this product and related activities are to be in accordance with the substance and procedures reflected in the Accelerated Approval Regulations referenced above.

The final printed labeling (FPL) must be identical to the November 10, 1995 draft labeling which includes draft carton and container labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit fifteen copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved NDA 50-718. Approval of this labeling by FDA is not required before it is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any deficiencies that may occur.

Please submit one market package of the drug when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Leslie Vaccari, Project Manager, at (301) 594-5778.

Sincerely yours,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE: Labeling